

Declaration of Conformity

MANUFACTURER: ADDRESS: EasyDx, Inc. dba LifeHealth also trading as LifeHealth
2656 Patton Road
Roseville, Minnesota 55113 - USA

PRODUCT TYPE: Blood Analysis System

MODELS: IRMA Vet (model LH)

We hereby declare under our sole responsibility that the products listed attachment II are in conformity to the EMC Directive [2014/30/EU], Low Voltage Directive [2014/35/EU], RED Directive [2014/53/EU], and RoHS Directive [2011/65/EU] as well as the consensus standards listed in attachment I.



Jim Kurkowski
Chief Technical Officer

March 23, 2018

Date

Attachment I: Harmonized Standards

Electromagnetic Compatibility (EMC) Directive [2011/65/EU]	
EN 55011:2009 +A1:2010 (CISPR 11:2009/a1:2010)	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
EN 61326-1:2013 IEC 61326-1:2012	Electrical equipment for the measurement, control and Laboratory use – EMC Requirements, Part 1: General Requirements
IEC 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
RED Directive [2014/53/EC]	
EN 300 328-1 V2.1.1	Wideband Transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 300 440-1 V1.6.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Part 1: Technical characteristics and test methods
EN 300 440-2 V1.4.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive
EN 301 893 V2.1.1	5 GHz RLAN; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 489-1 V1.9.2	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common Technical Requirements
EN 301 489-17 V2.1.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems
EN 301 489-3 V1.5.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz
Low Voltage Directive [2014/35/EU]	
IEC 61010-1:2010	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
IEC 61010-2-010:2014	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011	Information Technology Equipment - Safety - Part 1: General Requirements
EN 62311:2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
RoHS Directive [2011/65/EU]	
EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Attachment II: Products Covered

IVD	
555700V	Irma Vet Blood Analysis System

The system consists of the following

Instrument Kit	
443950V	Irma Blood Analyzer, Base
428570V	Irma Blood Analyzer, Tablet Host
S022-1001X	Power Supply ¹
401000	Power Cord ¹
432150	Temperature Calibration Card
Cartridges/Reagents	
039903V	Cartridge, 25pk, Combo
048103V	Cartridge, 25pk, Blood Gas (BG)
048400V	Cartridge, 25pk, Hematocrit and Electrolyte (H3)
039903-10V	Cartridge, 10pk, Combo
048103-10V	Cartridge, 10pk, Blood Gas (BG)
048400-10V	Cartridge, 10pk, Hematocrit and Electrolyte (H3)
Accessories	
040500	Capillary Device, 50pk